K002080

NOV 16 2000

510(k) Summary of Safety and Effectiveness Information
BCS™ Coagulation System
July 7, 2000

Dade Behring Inc.
7739 NW 48th Street
Miami, FL 33166
Contact Person: Radames Riesgo at 305.392.5639 or by facsimile at 305.392.5638.

Trade or Proprietary Name: Behring Coagulation System (BCS™)

Common or Usual Name: Automated Coagulation Instruments

Classification Name: Coagulation instrument (21 CFR §864.5425)

Registration Number:

Manufacturing Site
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
Marburg, Germany 9610806

Distributor
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

The BCS is substantially equivalent in intended use to the manual tilt-tube method recommended in the GradiLeiden V Test, Gradipore Ltd., Australia, which was cleared for Factor V Leiden assay by FDA under Document Control No. K992456.

As demonstrated by clinical correlation studies, the performance claims of the proposed device are similar to the predicate device. During those studies, specimens were evaluated from normal individuals and from patients with Factor V (Leiden) deficiency. The following summary shows the results of the comparison studies between the proposed and the predicate device.

Summary of Method Comparison Studies Between the BCS™ and the Manual Procedure

Test	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
Factor V Leiden	52	0.906	Y = 0.82X – 0.05

Summary of Precision Studies BCS™ Coagulation System

Assay	Control Level	n	Mean	Within Run %CV	Between Run %CV	Total %CV	Max. Error Criteria %CV
GradiLeiden V Test	CPN	40	2.4	3.5	2.7	4.3	10
	P2-Pool	40	1.3	1.1	4.4	4.6	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 6 2000

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
DADE BEHRING, INC.
7739 NW 48th Street, Suite 120
Miami, Florida 33166

Re: K002080
Trade Name: Behring Coagulation System (BCS™)
Regulatory Class: II
Product Code: JPA
Dated: September 19, 2000
Received: September 20, 2000

Dear Mr. Riesgo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Statement

510(k) Number (if known): K002080

Device Name: Behring Coagulation System

Indications for Use:

The Behring Coagulation System (BCS) is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Antithrombin IIIa
- Batroxibin
- D-dimer
- Deficient Plasmas
- Derived Fibrinogen
- Factor V Leiden
- Fibrinogen
- Heparin
- Plasminogen
- Protein C-clotting
- Protein C-chromogenic
- Thrombin Time
- von Willebrand factor

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002080

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)